



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Nashville District Office

D1290 B

297 Plus Park Blvd.  
Nashville, TN 37217

March 26, 1997

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WARNING LITTER-97-NSV-03

Facility ID# 113167

Bill Wise, Clinical Director  
Columbia Four Rivers Medical Center  
1015 Medical Center Parkway  
Selma, AL 36701

Dear Mr. Wise:

Your facility was inspected on March 7, 1997 by a representative of the State of Alabama acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

LEVEL 1

No processor QC records were present: [REDACTED] OR [REDACTED] Room ID = ONE.

The specific deficiency noted above appeared under the "Level 1" heading on your MQSA Facility Inspection Report, which was given to you by your inspector. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 3 repeat noncompliance that was listed on the List of Observations as follows:

Level 3 (Repeat)

The medical audit system did not have the potential to obtain all pathology.

*Handwritten:*  
3/24/97  
JCH

Also included on the List of Observations were the following items listed as "Documents Pending":

1. Radiologic technologist's certification: [REDACTED]
2. Radiologic technologist's license: [REDACTED]

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and to properly initiate permanent corrective actions.

If you fail to properly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- \* impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- \* suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- \* seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- \* the specific steps you have taken to correct all of the violations noted in this letter;
- \* each step your facility is taking to prevent the recurrence of similar violations.

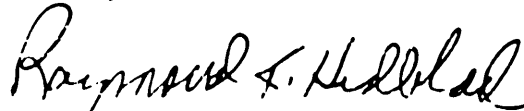
If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Columbia Four Rivers Medical Center - Page 3

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, C.S.O., at 615/781-5380, extension 144.

Sincerely,

A handwritten signature in black ink, appearing to read "Raymond K. Hedblad". The signature is fluid and cursive, with the first name "Raymond" being more prominent.

Raymond K. Hedblad  
Director, Nashville District

cc: State of Alabama, Dept. of Pub. Hlth, Div. of Rad. Control